UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,137	12/23/2005	Matthias Vennemann	27098U	5622

34375 7590 07/19/2011
NATH & ASSOCIATES PLLC
112 South West Street
Alexandria, VA 22314

EXAMINER	
DESAI, RITA J	
ART UNIT	PAPER NUMBER
1625	
MAIL DATE	DELIVERY MODE
07/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/562,137	VENNEMANN ET AL.
	Examiner	Art Unit
	RITA DESAI	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/10 has been entered.

Claims pending 1-14, 17-20 are pending.

The withdrawn claims 18-20 have been rejoined, as the compounds are otherwise found to allowable, except for minor issues as given below.

Election/Restrictions

The claims have not been amended to the elected group.

The elected group I in the response filed 3/19/09 is drawn to compounds and pharmaceutical compositions wherein R2 and R3 do not form a ring and Nor do any other R form a ring.

Applicants claims still includes R4 and R5 together forming a 1-4C-alkylene bridge.

Response to the arguments:-

REJECTION OF CLAIMS 1-3 UNDER 35 USC § 112
The applicants have amended the claims to make it clearer. There are however new rejection see below.

REJECTION OF CLAIMS 1-8, 10-14 AND 17 UNDER 35 USC § 103(a)

The rejection of claims 1-8, 10-14 and 17 under 35 USC § 103(a) as being unpatentable over Zhanget al. (WO 2003/51877) in view of Bauser et al. (WE) 03014117) and Bauser et al. (WO 03014116). Has been withdrawn.

Applicants argue that the examiner has not made a prima facie rejection and the applicants have issues with the statements for the declaration.

Applicants have amended the claims to include R1 to be a H. The compounds now compared in the declaration comparison now fall within the scope of the claimed invention. The rejection has been withdrawn.

The rejection over the ODP has also been withdrawn as applications 10/562149, 11/794497 and 11/794494 have been abandoned.

New Rejection:-

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1-14, 17-20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "R711" on page 3 of 42. There is insufficient antecedent basis for this limitation in the claim.

Rejection on the rejoined claims 18-20.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds to have some PDE inhibition activity, does not reasonably provide enablement for treating neurologic or psychiatric disorders or for regulating fertility, or for treating diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The Breadth of the claims :- the claims 18-20 are drawn to treat any neurological or any psychiatric disorder and/or regulate fertility and/or treat diabetes.

State of the art: there is still no drug available that can treat a laundry list of disorders. Just neurological disorders can include numerous disorders.

The scope of "neurological disorders" cannot be deemed enabled. The term "neurological disorders" covers a broad array of different disorders that have different modes of action and

different origins. The term covers such diverse disorders as Alzheimer's Disease; Parkinson's Disease; ALS and variants such as forms of ALS-PDC; Gerstmann-Straussler-Scheinker Disease (GSS); Pick's Disease; Diffuse Lewy Body Disease; Hallervordon-Spatz disease; progressive familiar myoclonic epilepsy; Corticodentatonigral degeneration; progressive supranuclear palsy (Steele-Richardson-Olszewski); Huntington's disease; more than a dozen dementias collectively called "frontotemporal dementia and Parkinsonism linked to chromosome 17" (FTDP-17); Tourette's syndrome; Shy-Drager syndrome; Friedrich's ataxia and other spinocerebellar degenerations; Olivopontocerebellar atrophy (OPCA); spasmotic torticollis; Striatonigral degeneration; various types of torsion dystonia; certain spinal muscular atrophies, such as Werdnig-Hoffmann and Wohlfart-Kugelberg-Welander; Hereditary spastic paraplegia, Primary lateral sclerosis; peroneal muscular atrophy (Charcot-Marie-Tooth); Creutzfeldt-Jakob Disease (CJD); Hypertrophic interstitial polyneuropathy (Dejerine-Sottas); retinitis pigmentosa; Leber's Disease; and Hypertrophic interstitial polyneuropathy. These exhibit a very broad range of effects and origins. For example, some give progressive dementia without other prominent neurological signs, such as Alzheimer's disease, whereas other dementias have such signs, such as Diffuse Lewy Body Disease. Some give muscular wasting without sensory changes, e.g. ALS, and some do have the sensory changes such as Werdnig-Hoffmann. Some are abnormalities of posture, movement, or speech, such as Striatonigral degeneration, and other are progressive ataxias, such as OPCA. Some are linked to tau mutations, such as Alzheimer's disease and FTDP-17, and other such as Parkinson's clearly do not. Some affect only vision such as retinitis pigmentosa. Even within those that fall into the same category of effects, there are often striking differences. For example, Alzheimer's disease and Pick's disease both give

progressive dementia without other prominent neurological signs. However, the characteristic Alzheimer's neurofibrillary tangles are not seen in Pick's Disease, which has straight fibrils, as opposed to the paired helical filaments of Alzheimer's disease. Pick's Disease gives lobal atrophy, not seen in Alzheimer's disease. There are differences in origins, even with what little is known. Thus, among progressive dementias, CJD is definitely caused by an infectious agent; so far as can be determined, this is not so for Huntington's disease. Even among the hereditary disorders, the origins are different. Thus, FTDP-17 comes from chromosome 17, Huntington's disease from 4, and the neurodegenerative disorder that people with Down's syndrome develop later in life is presumably connected in some way to 21.

The great majority of these have no treatment at all, and of those that do, none or virtually none have been treated with such inhibitors as are disclosed here. The great diversity of diseases falling within the "neurodegenerative disorder" category means that it is contrary to medical understanding that any agent (let alone a genus of trillions of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task. Further, what little success there has been does not point in this direction. Thus, what very few treatments that the massive research effort on Alzheimer's disease has produced are means of providing acetylcholinesterase inhibition, unrelated to the mechanism of action in this case.

While the present rejection is enablement, the Board of Patent Appeals and Interferences upheld a utility rejection concerning cancer treatment claims when "the examiner's doubt appears to be reasonable in light of the unique utility" *Ex parte Jovanovics, Szasz, Kellner, Nemeth, Relle, Bittner, Deszeri, and Eles*, 211 USPQ 907. It held that "a method of vaccinating humans or

animals to achieve immune protection against pathogenic E. coli" was "sufficiently unusual to justify an examiner's requiring substantiating evidence." *Ex parte Maas* USPQ2d 1762. It held that claims to cancer treatment "sufficiently unusual to justify the examiner's requirement for substantiating evidence.", *Ex parte Busse,* 1 USPQ2d 1908. In an intereference case, it held that the losing applicant lacked utility because "[t]here is no evidence that there was a correlation between the tests and the treatment of arthritis or for any other useful purpose." *Hoffman v. Klaus* 9 USPQ2d 1657. It upheld an enablemen rejection, writing that , "[i]n the absence of animal studies and in the absence of any correlation between the studies conducted in vitro and the diseases to be treated, we agree with the examiner that there is no evidence to justify the contention that the claimed compositions can be useful in the treatment of diseases." *Ex parte Powers*, 220 USPQ 924. The U.S. Patent and Trademark Office Commissioner of Patents held that "[t]he examiner does not need to provide reasons why this speculative assertion should not be believed. The mere fact that the art of cancer chemotherapy is highly unpredictable places the burden on applicants to provide a basis for believing the speculative statements", *In re Application of Hozumi et al.*, 226 USPQ 353. It wrote that cancer treatment claims are allowable if Applicants "can provide evidence showing substantial activity in screening tests customarily used and accepted as predicative of human activity for the type of chemical tested. Of course, the evidence presented must be commensurate with the scope of utility asserted", *Ex parte Aggarwal* 23 USPQ2d 1334.

Applicants also further claim treating diabetes and regulating fertility.

Lack of Guidance in the specifications:-

Compounds according to the invention have been made. The assay test is noted. There is some IC50 values for PDE-10 inhibition.

While screening test in an enzyme assay provides data in picking and choosing lead compounds for further testing, screening test per se does not provide sufficient operational guidance in an "individual" in patho-physiological environment to treat a laundry list of disorders.

Predictability in the art:-

Pharmaceutical art is highly unpredictable.

As can be seen from applicants declaration too a difference of a methyl group in a certain positions gives unexpected results.

Taking all the above factors, the examiner believes that the compounds are not enabled to treat all the various disorders as claimed with out any "undue" experimentation.

Genetech Inc Vs Nova Nordisk 42 USPQ 2d 1001.

"A patent is not a hunting license. It is not a reward for search but compensation for its successful conclusion and patent protection is granted in return for an enabling disclosure of an invention , not for vague intimations of general ideas that may or may not be workable."

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that,

based on the evidence regarding each of the above factors, the specification, at the time the application was flied, would not have taught one skilled in the art how to

make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Conclusion

Claims 1-14, 17-20 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RITA DESAI whose telephone number is (571)272-0684. The examiner can normally be reached on Maxi- flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

July 15, 2011.